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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,879	10/01/2003	Vladimir Z. Volloch	A32367-PCT USA	9476
21003	7590	03/06/2006	EXAMINER	
BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			BRADRICK, THOMAS DALE	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

09/936,879

**Applicant(s)**

VOLLOCH, VLADIMIR Z.

**Examiner**

Thomas D. Bradrick

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 14-18 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-13 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1-19-06</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 1-20 are pending. Claims 11-13 and 19 are being examined on the merits. Claims 1-10, 14-18 and 20 are withdrawn from examination as being drawn to non-elected inventions. Election was made with traverse in the response filed January 19, 2006. Applicant's claim to priority to provisional application 60/125,046 is acknowledged.

### ***Election/Restrictions***

Applicant's election with traverse of claims 11-13 in the reply filed on January 19, 2006 is acknowledged. The traversal is on the ground(s) that claim 19, which relates to a method of treating a proliferative disorder by modulating the activity of heat shock protein 72, should be examined with elected claims 11-13. Applicant argues that examining claims 11-13 and 19 together would not place an additional search burden on the examiner. Applicant's argument is found to be persuasive and, as a consequence, claim 19 is being rejoined to claims 11-13 and is being examined on the merits herewith.

### ***Specification***

The specification should be checked for errors. Errors include (presumably) misspelling "lost" as "cost" (p. 8, l. 18) and "rate" as "ate" (p. 9, l. 11). The preposition "of" is also missing from l. 27, p. 18.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

***Written Description***

Claims 11-13 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 11-13 and 19 are broadly drawn to methods for inhibiting cell proliferation and treating a proliferative disorder comprising administering an inhibitor of heat shock protein 72 (hsp72) activity and modulating hsp72 activity, respectively.

In contrast, the specification only provides guidance for screening hsp72 antagonists or inhibitors. No such antagonists or activity modulators are actually disclosed and no guidance is presented regarding the structure/function relationship between any antagonists or modulators. There is no clear indication that modulating hsp72 activity would serve as an effective treatment of proliferative disorders. Thus it is not apparent that the disclosure provided is reasonably predictive of the ability of said activity modulators to treat said disorders.

Given the breadth of the claims and lack of guidance as discussed above, the specification fails to provide an adequate written description of the claimed invention or show that applicant was in possession of it at the time application was made.

See *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997).

***Indefinite***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 19 is drawn to a method for treating a proliferative disorder comprising modulating the activity of hsp72. Which specific proliferative disorders are to be so treated, however? Applicant has not specified.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 11 and 13 are rejected under 35 U.S.C. 102(a) as being unpatentable over Neuhofer *et al.* [U].

Claim 11 is drawn to a method for inhibiting the proliferation of cells, said method comprising administering an inhibitor of hsp72 activity. Claim 13 is drawn to the method of claim 11 wherein the inhibitor of hsp72 activity is an hsp72 antisense nucleic acid.

Neuhofer *et al.* [U] disclose transfecting a pcDNA-based construct comprising 322 bases of the hsp72 open reading frame in antisense orientation, into Madin-Darby canine kidney cells (Abstract, ll. 17-20). Therefore, Neuhofer *et al.* [U] inherently anticipate a process of administering an hsp72 antisense nucleic acid for the recited purpose of inhibiting the proliferation of cells.

***Furthermore,***

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11 is rejected under 35 U.S.C. 102(b) as being unpatentable over Geng *et al.* [V] in light of Kiang *et al.* [W].

Claim 11 is drawn to a method for inhibiting the proliferation of cells, said method comprising administering an inhibitor of hsp72 activity.

Geng *et al.* [V] disclose treating human blood monocytes with the protein kinase A inhibitor *N*-[2-(*p*-Bromocinnamylamino)ethyl]-5-isoquinolinesulphonamide (H89) (Abstract). Kiang *et al.* [W] are relied upon to demonstrate that H89 inhibits hsp72 synthesis in human breast cancer MDA-MD-231 cells (Abstract, l. 7).

Therefore, Geng *et al.* [V] inherently anticipate a process of administering an hsp72 inhibitor for the recited purpose of inhibiting the proliferation of cells.

It is noted that Kiang *et al.* [W] was published after the earliest priority date of the instant application. However, this reference is used solely to demonstrate the inherent activity of H89 to inhibit hsp72 activity.

Claims 11 and 12 are rejected under 35 U.S.C. 102(b) as being unpatentable over Riabowol *et al.* [X].

Claim 11 is described above. Claim 12 is drawn to the method of claim 11 wherein the inhibitor of hsp72 activity is an anti-hsp72 antibody.

Riabowol *et al.* [X] disclose introducing affinity-purified monoclonal antibodies to hsp70 into rat fibroblasts by microinjection (Abstract). (Riabowol *et al.* [X] also teach that hsp70 is comprised of two forms: hsp72 and hsp73 (Introduction).) Riabowol *et al.* [X] therefore inherently anticipate a process of administering anti-hsp72 antibody for the recited purpose of inhibiting the proliferation of cells.

Claims 11 and 13 are rejected under 35 U.S.C. 102(b) as being unpatentable over Nakano *et al.* [U2].

Claim 11 is described above. Claim 13 is drawn to the method of claim 11 wherein the inhibitor of hsp72 activity is an hsp72 antisense nucleic acid.

Nakano *et al.* [U2] disclose treating isolated adult feline cardiocytes with a 14-mer phosphorothioate antisense to hsp72 (Abstract, Methods and Results subsection). Nakano *et al.* [U2] therefore inherently anticipate a process of administering an hsp72 antisense nucleic acid for the recited purpose of inhibiting the proliferation of cells.

Claim 19 is rejected under 35 U.S.C. 102(b) as being unpatentable over Hirakawa *et al.* [V2] in light of Caprioli *et al.* [W2].

Claim 19 is drawn to a method for treating a proliferative disorder, said method comprising modulating the activity of hsp72.

Hirakawa *et al.* [V2] disclose administering geranylgeranylacetone (GGA) to male Wister rats (bottom of p. 347). Caprioli *et al.* [W2] is relied upon to demonstrate that GGA induces expression of hsp72 in rat retinal ganglion cells (Abstract and Conclusions). Therefore, Hirakawa *et al.* [V2] inherently anticipate a process of modulating hsp72 activity for the recited purpose of inhibiting the proliferation of cells.

It is noted that Caprioli *et al.* [W2] was published after the earliest priority date of the instant application. However, this reference is used solely to demonstrate the inherent activity of GGA to modulate hsp72 activity.

Note: claim preamble language may not be treated as a limitation where it merely states an intended use of the system and is unnecessary to define the invention, the U.S. Court of Appeals for the Federal Circuit ruled May 8 (Catalina Marketing Int'l Inc. v. Coolsavings. com Inc., Fed. Cir., No. 01-1324, 5/8/02).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Bradrick whose telephone number is 571-272-8139. The examiner can normally be reached Monday through Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached at 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

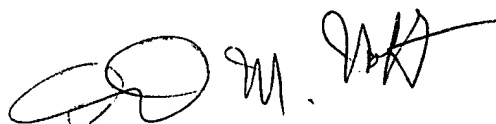


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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